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Food and Drug Administration  
Rockville MD 20857Re: Bepadin/Vascor  
Docket No. 91E-0106

The Honorable Harry F. Manbeck Jr.  
Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 30,577, filed by Rion Laboratories CERM under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Bepadin and Vascor, the human drug products claimed by the patent.

The total length of the review period for Bepadin is 4,658 days. Of this time, 2,108 days occurred during the testing phase and 2,550 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 30, 1978.

The applicant claims March 24, 1977 as the date the investigational new drug application (IND) for the drug became effective. However, FDA records indicate that IND No. 13,238 became effective on March 30, 1978.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: January 5, 1984.

The applicant claims December 28, 1983 as the date the new drug application (NDA) was initially submitted. However, FDA records indicate that NDA No. 19-001 was received on January 5, 1984.

3. The date the application was approved: December 28, 1990.

FDA has verified the applicant's claim that NDA 19-001 was approved on December 28, 1990.

The total length of the review period for Vascor is 3,207 days. Of this time, 649 days occurred during the testing phase and 2,558 days occurred during the approval phase.

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These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 20, 1982.

The applicant claims March 17, 1982 as the date IND no. 19,896 became effective. However, FDA records indicate that the IND became effective on March 20, 1982.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: December 28, 1983.

FDA has verified the applicant's claim that the NDA was received on December 28, 1983.


3. The date the application was approved: December 28, 1990.

FDA has verified the applicant's claim that NDA 19-002 was approved on December 28, 1990.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

  
Stuart L. Nightingale, M.D.  
Associate Commissioner  
for Health Affairs

cc: Kevin B. Clarke, Esq.  
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